

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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|--|---|---|------------------|
| Applicant's or agent's file reference BNPA0501.PCT | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/KR2005/000889 | International filing date (<i>day/month/year</i>) 25 March 2005 (25.03.2005) | Priority date (<i>day/month/year</i>) 25 March 2004 (25.03.2004) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant BIONEER CORPORATION | | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

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|---|---|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Date of issuance of this report 26 September 2006 (26.09.2006) Authorized officer <p style="text-align: center; font-weight: bold;">Philippe Becamel</p> e-mail: pt12@wipo.int |
|---|---|

PATENT COOPERATION TREATY

REC'D 19 SEP 2005

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

SEO Keun-Bok
1003 ho, Sungji-Heights III Bldg.,
642-6, Yeoksam-Dong, Gangnam-gu
135-080 Seoul
Republic of Korea

Date of mailing
(day/month/year)

15 September 2005 (15.09.05)

Applicant's or agent's file reference
BNPA0501.PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/KR 2005/000889

International filing date (day/month/year)

25 March 2005 (25.03.2005)

Priority Date (day/month/year)

25 March 2004 (25.03.2004)

International Patent Classification (IPC) or both national classification and IPC

C12Q 1/68

Applicant

BIONEER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Cont. No. I Basis of the opinion
- ☐ Cont. No. II Priority
- ☐ Cont. No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Cont. No. IV Lack of unity of invention
- ☒ Cont. No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Cont. No. VI Certain documents cited
- ☐ Cont. No. VII Certain defects in the international application
- ☐ Cont. No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ AT

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Continuation No. I

Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed.
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion was carried out on the basis of:
 - a. type of material: table(s) related to the sequence listing
 - b. format of material: in written format
 - c. time of filing/furnishing: contained in the international application as filed

Continuation No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-----------------------------|-----|
| Novelty (N) | Claims 1-34 | YES |
| | Claims ---- | NO |
| Inventive step (IS) | Claims 8, 20, 33 | YES |
| | Claims 1-7, 9-19, 21-32, 34 | NO |
| Industrial applicability (IA) | Claims 1-34 | YES |
| | Claims ---- | NO |

2. Citations and explanations:

The following documents are cited:

D1: US 2003/0143591 A1 (DAVIES et al.) 31.07.2003

D2: Appl Environ Microbiol. 2003, Vol. 69, No. 8, pages 4753-4759

D1 relates to methods to detect and/or quantify nucleic acid analytes. The methods involve nucleic acid probes with covalently conjugated dyes, which are attached either at adjacent nucleotides or at the same nucleotide of the probe and linker molecules to attach the dyes to the probes. The nucleic acid probes generate a fluorescent signal upon hybridization to complementary nucleic acids based on the interaction of one of the attached dyes, which is either an intercalator or a DNA groove binder, with the formed double stranded DNA.

A nucleic acid probe functions e.g. as a primer in a polymerase chain reaction. It may be used in a real time PCR.

D1 discloses a nucleic acid probe comprising a nucleic acid that is derivatized with two or more non-identical covalently attached dyes. The primer/probe of present application needs just one fluorescent dye which is easier to produce. But the concept of watching the change of fluorescence during the PCR with suitable primers/probes is obvious from D1. The dependent claims of present application concern typical dyes, PCR products and PCR conditions which are well known. Thus, the subject-matters of the claims 1-7, 9-19, 21-32 and 34 are not inventive.

D2 concerns real-time PCR. According to D1 real-time PCR provides a means of detecting and quantifying DNA targets by monitoring PCR product accumulation during cycling as indicated by increased fluorescence. A number of different approaches can be used to generate the fluorescence signal. Double-stranded DNA intercalating dye, 5'-exonuclease, and hybridization probes (fluorescence resonance energy transfer)-were evaluated for use in a real-time PCR assay to detect bacteria. The three assays utilized the same amplification primers to produce an identical amplicon. This amplicon spans a region of the B. abortus genome. All three assays were of comparable sensitivity, providing a linear assay over 7 orders of magnitude (from 7.5 ng down to 7.5 fg). Also D2 demonstrates that idea of a real time PCR where fluorescence is changing is obvious. Accordingly, this document anticipates the subject-matters of the claims 1-7, 9-19, 21-32 and 34 as well.

The subject-matters of claims 8, 20, and 33 are new and inventive. With the probes/primers of said claims and the corresponding real time methods very good results are achieved. This fact is supported by the examples (see also figures) very well.

The subject-matters of claims 1-34 are obvious.